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December 13, 2004

Division of Dockets Management 5630 Fishers Lane, Room 1061 Rockville, MD 20852

RE: Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504

Dear Sir or Madam:

The AVMA applauds the initiative taken by FDA in addressing the food borne threat posed by Salmonella Enteritidis (SE). The proposed rule contains well thought out, evidence based mitigation measures that should, if properly implemented, achieve a reduction in egg contamination with SE. However, AVMA is concerned that the proposed rule is overly prescriptive and will cause an unnecessary financial impact to industry and government while restricting producers' abilities to utilize the most current technologies and scientific information to achieve and maintain an "SE negative status".

We recognize the success of current on farm quality assurance (OA) programs. The food safety good production practices included in these QA programs have been proven to be a valuable tool in the effort to reduce Salmonella Enteritidis in shell eggs. Therefore, the AVMA recommends that the proposed rule should be amended to an "outcome (performance) based" design that allows for variation in methods of implementation as science evolves in the area of SE prevention. This would include the following:

- A specified frequency of environmental testing for all producers with a required negative status outcome.
- Positive SE environment facilities would be followed with egg testing and diversion of eggs from positive flocks.
- As long as producers maintained negative poultry houses, additional SE prevention measures would not be required.
- The rule is applied to all commercial egg producers (including flocks with fewer than 3000 laying hens).
- Require use of pasteurized eggs for >3 pooled eggs in commercial settings.

At the same time, the AVMA recommends that FDA use the most current molecular epidemiological methods to discriminate the possible sources of SE infections (the current New York model as an example).

In order to fully implement this rule, the AVMA strongly recommends that a state cooperative program for funding be part of the overall plan thus utilizing the expertise of state animal health officials in implementing any new SE rule.

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Recognizing the expertise of USDA APHIS in working with animal producers, veterinarians, and the SE program, the AVMA recommends that USDA implement the program through a memorandum of understanding established between the USDA and the FDA with appropriate funding transferred to USDA.

These measures would allow the industry to move toward a safer final product while allowing flexibility in implementation as technology and scientific information improve. We strongly believe these recommendations will greatly reduce illness attributable to SE from the consumption of contaminated shell eggs. The AVMA remains committed to partnering with industry and government to provide a safer food supply to the consumer.

Sincerely,

Executive Vice President

BWL/FSAC/CPHRVM/LPV

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